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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,533

09/15/2005

Firelli Alonso-Caplen

AM100395

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7590

03/28/2008

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EXAMINER

HURT, SHARON L

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

03/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,533	Applicant(s) ALONSO-CAPLEN ET AL.	
	Examiner SHARON HURT	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Feb. 9, 2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3, in the reply filed on January 11, 2008 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire patent application can be made without serious burden. Applicants argue that the claims of Group I are fundamentally related to the claims of Groups II-V, therefore the claims should not pose an undue burden on the Examiner. This is not found persuasive because the different groups are drawn to different products and processes for producing the products. Different products would require a different search in the art as well as different processes would require an independent search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 11, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (Journal of Virology, Apr. 1998, Vol. 72, No. 4, pages 2871-2880) in view of Firestone et al. (Virology, 1996, Vol. 225, pages 419-422, Article No. 0618, Short Communication).

The claimed invention is drawn to a method of identifying an attenuated respiratory syncytial virus (RSV) strain that produces high yields of RSV surface glycoproteins F and G when compared to parent strain A2. The method comprises: providing a eukaryotic cell culture, infecting the cell culture with a live, attenuated RSV; and determining the glycoprotein concentration, wherein at least five-fold increase in glycoprotein concentration is an indication that the attenuated strain produces high yields of RSV F and G glycoproteins compared with the parent A2 strain, wherein the RSV mutant strain is *cpts*-248/404, wherein the eukaryotic cells are VERO, MRC-5, FRhl, CEF or PER.C6 cell culture.

Johnson et al. (hereinafter Johnson) teaches the G glycoprotein has been implicated as an RSV antigen that promotes activation of the Th2 CD4+ T-lymphocyte and induces eosinophilic infiltrates in the lung following RSV challenge (page 2871, 1st column, 1st paragraph). Johnson teaches the large glycoprotein G serves as the attachment protein of RSV and is one of the major glycoproteins expressed in the membrane of the virus. The protein is expressed on the surface of the infected cell and secreted into the extracellular environment (page 2871, 1st column, 2nd paragraph). Johnson also teaches a method of purifying and measuring the secreted RSV G protein from RSV A2 strain (page 2872, 1st column, 3rd paragraph and page 2873, 1st column, 1st paragraph). Johnson does not teach an attenuated RSV, mutant strain *cpts*-248/404 or using VERO cells.

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Firestone et al. (hereinafter Firestone) teaches a live attenuated RSV strain, *cpt*-248/404 mutant, differs from its wild-type RSV strain A2 by increased G when passaged in VERO cell culture (Abstract and page 420, 2nd column). Firestone teaches attenuating RSV and the comparison of wild-type RSV A2 grown in HEp-2 cells, cold-passages *cp*-RSV, and temperature-sensitive *cpts*-248 (Abstract and page 2872, 1st column, 2nd paragraph). Firestone teaches how the *cpts*-248/404 mutant differs from its wild-type RSV A2/HEK7 parent (Abstract). Firestone also teaches the predominant nucleotide in *cpts*-248/404 is G and that this can be used for identification of the *cpts*-248/404 mutant (pages 421-422, joining paragraph).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to identify a high glycoprotein producing RSV. The person of ordinary skill in the art would have been motivated because Johnson teaches the importance of the glycoprotein and how to measure the glycoprotein, and Firestone teaches a comparison of attenuated RSVs to the wild-type RSV. One reasonably would have expected success because of the teachings of Johnson and Firestone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is (571)272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

March 13, 2008

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648